IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Confirmation No.: 1688

BHATARAH et al. Art Unit: 1617

Appl. No.: 10/505,137 Examiner: Karol, Jody Lynn

§ 371 Date: April 25, 2005 Atty. Docket: 2544.1120000/RWE/SLE

For: Solvent-Based Sterilization
Of Pharmaceuticals

First Supplemental Information Disclosure Statement

under 37 C.F.R. § 1.97(c)

Mail Stop RCE

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Sir:

Listed on accompanying IDS Form, PTO/SB/08A, is a document that may be considered material to the patentability of this application as defined in 37 C.F.R. §1.56, and in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.97 and 1.98. This First Supplemental Information Disclosure Statement is a continuation of Applicants' Information Disclosure Statement filed on July 10, 2008.

A copy of document FP22 is submitted.

In accordance with 37 C.F.R. § 1.98(a)(3), Applicants' undersigned representative submits the following discussion of the relevance of the non-English language document FP22.

Document FP22, EP 0364 842 A1, is not in the English language. The document FP22 was cited in a search report by a foreign patent office in counterpart International Application No. PCT/GB03/00702. Submission of an English language version of the

search report that indicates the degree of relevance found by the foreign office is provided as document NPL7, submitted with the Information Disclosure Statement filed on July 10, 2008, in satisfaction of the requirement for a concise explanation of relevance. See MPEP 609.04(a) and 1138 Official Gazette 37, 38.

Applicants have listed publication dates on the attached IDS Forms based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed before the mailing of a first
Office Action after the filing of a request for continued examination under 37 C.F.R. §
1.114. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed IDS Forms, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Stephanie L. Elmer Attorney for Applicants Registration No. 59,244

1100 New York Avenue, N.W. Washington, D.C. 20005-3934 (202) 371-2600

(202) 371-260 1027338_1.DOC